

UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF VIRGINIA  
CHARLOTTESVILLE DIVISION

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PBM PHARMACEUTICALS, INC. *et al.*  
Plaintiffs,

v.

Civil Action No. 3:14-cv-00016-GEC

METHOD PHARMACEUTICALS, LLC  
*et al.*  
Defendants.  
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**DEFENDANT MATTHEW SCOTT TUCKER'S ANSWER TO  
THIRD AMENDED COMPLAINT**

Defendant Mr. Matthew Scott Tucker ("Mr. Tucker"), through his undersigned attorneys, hereby answers the allegations of Plaintiffs' Third Amended Complaint ("TAC"), solely with respect to Mr. Tucker and not with respect to any other Defendant in the above-captioned matter, as follows:

1. Mr. Tucker lacks information sufficient to form a belief as to whether Plaintiffs' Donnatal brand of pharmaceutical products has helped improve the lives of individuals suffering from irritable bowel syndrome (IBS). Mr. Tucker admits that Paragraph 1 generally describes IBS.

2. Mr. Tucker admits that Plaintiffs distribute Donnatal in a liquid and a tablet formulation. Mr. Tucker denies the remaining allegations contained in Paragraph 2.

3. Mr. Tucker admits that phenobarbital is listed as an active ingredient in Donnatal. Mr. Tucker further admits that atropine, hyoscyamine, phenobarbital, and scopolamine are sometimes referred to as belladonna alkaloids and are also listed as active ingredients in Donnatal. Mr. Tucker lacks information sufficient to form a belief as to the remaining allegations contained in Paragraph 3 and on that basis denies them.

4. Mr. Tucker admits that the products at issue in this case are called Me-PB-Hyos. Mr. Tucker denies the remaining allegations contained in Paragraph 4.

5. Mr. Tucker admits that Plaintiffs purport to seek the relief described in Paragraph 5 but denies that Plaintiffs are entitled to the requested relief, or any relief whatsoever.

6. Mr. Tucker lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 6 and on that basis denies them.

7. Mr. Tucker lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 7.

8. Mr. Tucker is not required to respond to the allegations in Paragraph 8 because they relate to another defendant. To the extent a response is required, Mr. Tucker admits that Defendant Method Pharmaceuticals, LLC (“Defendant Method”), is a Texas limited liability company with its principal office at 2000 East Lamar Boulevard, Suite 600, Arlington, Texas 76006, and admits that Defendant Method is the labeler for the Me-PB-Hyos products at issue in this case.

9. Mr. Tucker admits the allegations contained in Paragraph 9.

10. Mr. Tucker is not required to respond to the allegations in Paragraph 10 because they relate to another defendant. To the extent a response is required, Mr. Tucker lacks knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations contained in Paragraph 10 and on that basis denies them.

11. Mr. Tucker is not required to respond to the allegations in Paragraph 11 because they relate to another defendant. To the extent a response is required, Mr. Tucker lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 11.

12. The allegations contained in Paragraph 12 are legal conclusions to which no response is required. To the extent a response is required, Mr. Tucker denies the allegations contained in Paragraph 12.

13. The allegations contained in Paragraph 13 are legal conclusions to which no response is required. To the extent a response is required, Mr. Tucker denies the allegations contained in Paragraph 13.

14. The allegations contained in Paragraph 14 are legal conclusions to which no response is required. To the extent a response is required, Mr. Tucker denies the allegations contained in Paragraph 14 as they relate to Mr. Tucker.

15. Mr. Tucker lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 15.

16. Mr. Tucker admits that Donnatal products are available by prescription only. Mr. Tucker denies all remaining allegations contained in Paragraph 16.

17. Mr. Tucker lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 17.

18. The allegations contained in Paragraph 18 purport to characterize amendments to the Federal Food, Drug and Cosmetic Act (the “FDC Act”) and therefore state legal conclusions to which no response is required. To the extent a response is required, Mr. Tucker states that applicable laws speak for themselves and any characterization thereof is denied. Mr. Tucker lacks information sufficient to form a belief as to the remaining allegations contained in Paragraph 18.

19. The allegations contained in Paragraph 19 purport to characterize a Federal Register notice, which speaks for itself, and any characterization thereof is denied.

20. Mr. Tucker admits that FDA conditionally approved abbreviated new drug applications for Donnatal tablet and elixir products. The remaining allegations in this paragraph purport to interpret the FDC Act and therefore state legal conclusions to which no response is required. To the extent a response is required, Mr. Tucker states that applicable laws and regulations speak for themselves and any characterization thereof is denied.

21. Mr. Tucker admits that on May 6, 1983, the FDA published a notice in the Federal Register regarding certain drug products, and that Donnatal was one of the drug products identified in the notice. The remaining allegations in paragraph 21 purport to characterize the Federal Register notice which speaks for itself and any characterization thereof is denied.

22. Mr. Tucker lacks information sufficient to form a belief as to the allegations contained in Paragraph 22 and on that basis denies them.

23. The allegations contained in Paragraph 23 purport to characterize and describe a legal process and state a legal conclusion to which no response is required. To the extent a response is required, Mr. Tucker denies the allegations of the first sentence of Paragraph 23. Mr. Tucker lacks information sufficient to form a belief as to the second sentence of Paragraph 23. Mr. Tucker admits that the NOOH process for Donnatal has not yet been completed.

24. Method lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 24 and on that basis denies them.

25. Mr. Tucker lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 25 and on that basis denies them.

26. Paragraph 26 constitutes Plaintiffs' characterization of the legal implications of an FDA Compliance Policy Guide, which speaks for itself and to which no response is required. To

the extent a response is required, Mr. Tucker denies any characterization of the Compliance Policy contained in Paragraph 26.

27. Paragraph 27 states a legal conclusion to which no response is required. To the extent a response is required, Mr. Tucker denies the allegations contained in Paragraph 27.

28. Mr. Tucker lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 28.

29. Mr. Tucker admits that on or around April 2, 2014, listings for the Me-PB-Hyos products appeared in Medi-Span. Mr. Tucker denies that a listing was attached as Exhibit A to the TAC. Mr. Tucker further states that there is no current Medi-Span listing.

30. Mr. Tucker admits that Medi-Span is a prescription drug and information and interactions database used nationwide by health care professionals, payers and pharmaceutical manufacturers to evaluate medications that are currently or will soon be on the market. Mr. Tucker denies the remaining allegations contained in Paragraph 30.

31. The allegations contained in Paragraph 31 constitute Plaintiffs' characterizations of Medi-Span policies regarding pharmaceutical equivalence and the assignment of a Generic Product Identifier ("GPI"), which speak for themselves and to which no response is required. To the extent a response is required, Mr. Tucker denies characterizations of Medi-Span policies contained in Paragraph 31.

32. Paragraph 32 states a legal conclusion to which no response is required. To the extent a response is required, Mr. Tucker lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 32.

33. Paragraph 33 constitutes Plaintiffs' characterization of the Medi-Span listings, which speak for themselves and to which no response is required. Mr. Tucker denies any characterization of the Medi-Span listings contained in Paragraph 33.

34. Mr. Tucker denies the allegations contained in Paragraph 34.

35. Mr. Tucker denies the allegations contained in Paragraph 35.

36. Paragraph 36 constitutes Plaintiffs' characterization of the Medi-Span listing process, which speaks for itself and does not require a response. To the extent a response is required, Mr. Tucker denies any characterization of the Medi-Span listing process contained in Paragraph 36.

37. Mr. Tucker admits that Defendant Method did not request from FDA, and FDA did not provide, an Approval Letter or approval number for products at issue. Mr. Tucker lacks knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations contained in Paragraph 37.

38. Mr. Tucker admits the allegations contained in Paragraph 38.

39. Mr. Tucker denies the allegations contained in Paragraph 39.

40. Mr. Tucker denies the allegations contained in Paragraph 40.

41. Mr. Tucker denies the allegations contained in Paragraph 41.

42. Mr. Tucker lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 42 and on that basis denies them.

43. Paragraph 43 states a legal conclusion to which no response is required. To the extent that a response is required, Mr. Tucker denies the allegations contained in Paragraph 43. Mr. Tucker states that Defendant Method listed its products' labeling on DailyMed, a database

maintained by the United States National Library of Medicine. Mr. Tucker further states that Defendant Method listed its products with the United States Food and Drug Administration.

44. Mr. Tucker admits that Medi-Span removed the Me-PB-Hyos listing. Mr. Tucker lacks knowledge or information sufficient to form a belief as to the truth or falsity of allegations contained in Paragraph 44 pertaining to First Databank. Mr. Tucker lacks knowledge or information to form a belief as to the truth or falsity of allegations contained in Paragraph 44 pertaining to the resubmission of Me-PB-Hyos for listing.

45. Mr. Tucker denies the allegations contained in Paragraph 45.

46. Mr. Tucker lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 46 and on that basis denies them.

47. Mr. Tucker lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 47 and on that basis denies them.

48. Mr. Tucker lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 48 and on that basis denies them.

49. Mr. Tucker denies that any introduction of Me-PB-Hyos would be “unauthorized.” Mr. Tucker lacks knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations contained in Paragraph 49 and on that basis denies them.

50. Mr. Tucker denies the allegations contained in Paragraph 50.

51. The allegations contained in Paragraph 51 constitute legal conclusions to which no response is required. To the extent a response is required, Mr. Tucker denies the allegations contained in Paragraph 51.

52. Mr. Tucker admits that counsel to PBM contacted Method. The remaining allegations contained in Paragraph 52 constitute characterizations of that interaction, and thus legal conclusions to which no response is required. To the extent a response is required, Mr. Tucker denies all characterizations contained in Paragraph 52.

53. The allegations contained in Paragraph 53 constitute legal conclusions to which no response is required. To the extent a response is required, Mr. Tucker denies the allegations contained in Paragraph 53.

54. Mr. Tucker lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 54, and on that basis denies them.

55. The allegations contained in Paragraph 55 are legal conclusions to which no response is required. To the extent a response is required, Mr. Tucker denies the allegations contained in Paragraph 55 as they relate to Mr. Tucker.

56. Mr. Tucker repeats and re-alleges his answers in paragraphs 1 through 55.

57. The allegations contained in Paragraph 57 are legal conclusions to which no response is required. To the extent a response is required, Mr. Tucker denies the allegations contained in Paragraph 57.

58. The allegations contained in Paragraph 58 are legal conclusions to which no response is required. To the extent a response is required, Mr. Tucker denies the allegations contained in Paragraph 58.

59. The allegations contained in Paragraph 59 are legal conclusions to which no response is required. To the extent a response is required, Mr. Tucker denies the allegations contained in Paragraph 59.



60. The allegations contained in Paragraph 60 are legal conclusions to which no response is required. To the extent a response is required, Mr. Tucker denies the allegations contained in Paragraph 60.

61. The allegations contained in Paragraph 61 are legal conclusions to which no response is required. To the extent a response is required, Mr. Tucker denies the allegations contained in Paragraph 61.

62. The allegations contained in Paragraph 62 are legal conclusions to which no response is required. To the extent a response is required, Mr. Tucker denies the allegations contained in Paragraph 62.

63. The allegations contained in Paragraph 63 are legal conclusions to which no response is required. To the extent a response is required, Mr. Tucker denies the allegations contained in Paragraph 63.

64. Mr. Tucker repeats and re-alleges his answers in paragraphs 1 through 63.

65. Mr. Tucker denies the allegations contained in Paragraph 65.

66. The allegations contained in Paragraph 66 are legal conclusions to which no response is required. To the extent a response is required, Mr. Tucker denies the allegations contained in Paragraph 66.

67. The allegations contained in Paragraph 67 are legal conclusions to which no response is required. To the extent a response is required, Mr. Tucker denies the allegations contained in Paragraph 67.

68. The allegations contained in Paragraph 68 are legal conclusions to which no response is required. To the extent a response is required, Mr. Tucker lacks knowledge or

information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 68 and on that basis denies them.

69. The allegations contained in Paragraph 69 are legal conclusions to which no response is required. To the extent a response is required, Mr. Tucker denies the allegations contained in Paragraph 69.

70. The allegations contained in Paragraph 70 are legal conclusions to which no response is required. To the extent a response is required, Mr. Tucker denies the allegations contained in Paragraph 70.

71. The allegations contained in Paragraph 71 are legal conclusions to which no response is required. To the extent a response is required, Mr. Tucker denies the allegations contained in Paragraph 71.

72. Mr. Tucker repeats and re-alleges his answers in paragraphs 1-71.

73. The allegations contained in Paragraph 73 are legal conclusions to which no response is required. To the extent a response is required, Mr. Tucker denies the allegations contained in Paragraph 73.

74. The allegations contained in Paragraph 74 are legal conclusions to which no response is required. To the extent a response is required, Mr. Tucker denies the allegations contained in Paragraph 74.

75. The allegations contained in Paragraph 75 are legal conclusions to which no response is required. To the extent a response is required, Mr. Tucker denies the allegations contained in Paragraph 75.

76. Mr. Tucker repeats and re-alleges his answers in paragraphs 1-75.

77. The allegations contained in Paragraph 77 are legal conclusions to which no response is required. To the extent a response is required, Mr. Tucker denies the allegations contained in Paragraph 77.

78. The allegations contained in Paragraph 78 are legal conclusions to which no response is required. To the extent a response is required, Mr. Tucker denies the allegations contained in Paragraph 78.

79. Mr. Tucker repeats and re-alleges his answers in paragraphs 1-78.

80. The allegations contained in Paragraph 80 are legal conclusions to which no response is required. To the extent a response is required, Mr. Tucker denies the allegations contained in Paragraph 80.

81. The allegations contained in Paragraph 81 are legal conclusions to which no response is required. To the extent a response is required, Mr. Tucker denies the allegations contained in Paragraph 81.

82. Mr. Tucker repeats and re-alleges his answers in paragraphs 1-81.

83. The allegations contained in Paragraph 83 are legal conclusions to which no response is required. To the extent a response is required, Mr. Tucker denies the allegations contained in Paragraph 83.

84. The allegations contained in Paragraph 84 are legal conclusions to which no response is required. To the extent a response is required, Mr. Tucker denies the allegations contained in Paragraph 84.

85. The allegations contained in Paragraph 85 are legal conclusions to which no response is required. To the extent a response is required, Mr. Tucker denies the allegations contained in Paragraph 85.

86. The allegations contained in Paragraph 86 are legal conclusions to which no response is required. To the extent a response is required, Mr. Tucker denies the allegations contained in Paragraph 86.

87. The allegations contained in Paragraph 87 are legal conclusions to which no response is required. To the extent a response is required, Mr. Tucker denies the allegations contained in Paragraph 87.

88. The allegations contained in Paragraph 88 are legal conclusions to which no response is required. To the extent a response is required, Mr. Tucker denies the allegations contained in Paragraph 88.

89. Mr. Tucker repeats and re-alleges his answers in paragraphs 1-88.

90. Mr. Tucker denies the allegations contained in Paragraph 90.

91. Mr. Tucker denies the allegations contained in Paragraph 91.

92. The allegations contained in Paragraph 92 are legal conclusions to which no response is required. To the extent a response is required, Mr. Tucker denies the allegations contained in Paragraph 92.

93. The allegations contained in Paragraph 93 are legal conclusions to which no response is required. To the extent a response is required, Mr. Tucker denies the allegations contained in Paragraph 93.

94. The allegations contained in Paragraph 94 are legal conclusions to which no response is required. To the extent a response is required, Mr. Tucker denies the allegations contained in Paragraph 94.

95. The allegations contained in Paragraph 95 are legal conclusions to which no response is required. To the extent a response is required, Mr. Tucker denies the allegations contained in Paragraph 95.

96. The allegations contained in Paragraph 96 are legal conclusions to which no response is required. To the extent a response is required, Mr. Tucker denies the allegations contained in Paragraph 96.

Mr. Tucker is not required to respond to Plaintiffs' Prayer for Relief. To the extent a response is required, Mr. Tucker denies the allegations set forth in the Prayer for Relief as they relate to Mr. Tucker and denies that Plaintiffs are entitled to any of the relief requested or any relief whatsoever.

Mr. Tucker denies all allegations in the TAC not specifically admitted above.

#### AFFIRMATIVE AND OTHER DEFENSES

For further and separate answer, Mr. Tucker alleges as follows:

##### FIRST DEFENSE

(Lack of Personal Jurisdiction)

The Court lacks personal jurisdiction over Mr. Tucker in this matter.

##### SECOND DEFENSE

(Failure to State a Cause of Action)

Each cause of action in the TAC fails to state a claim upon which relief can be granted.

##### THIRD DEFENSE

(First Amendment Rights)

The TAC, and each cause of action therein, is barred to the extent that the conduct alleged is protected by the free speech provision of the United States Constitution.

#### FOURTH DEFENSE

(Good Faith)

Each cause of action is barred, in whole or in part, because Mr. Tucker acted in good faith at all times.

#### FIFTH DEFENSE

(Lack of Intent)

Plaintiffs' claims based on alleged willful misrepresentations are barred because the representations and actions alleged were not intended to mislead or deceive consumers.

#### SIXTH DEFENSE

(Lack of Causation)

Each cause of action is barred, in whole or in part, because Plaintiffs have not sustained any injury or damage by reason of any act or omission on Mr. Tucker's part. To the extent that Plaintiffs suffered any damages, such damages were proximately caused by persons, entities, and/or factors or events other than Mr. Tucker and for which Mr. Tucker was and is not responsible.

#### SEVENTH DEFENSE

(Lack of Materiality)

Each cause of action is barred, in whole or in part, because Plaintiffs have not sustained any injury or damage by reason of any material act or admission on Mr. Tucker's part.

#### EIGHTH DEFENSE

(Lack of Reliance)

Plaintiffs' claims are barred, in whole or in part, because of the lack of reliance by consumers on any alleged misrepresentations by Mr. Tucker.

#### NINTH DEFENSE

(Lack of Awareness)

Plaintiffs' claims are barred, in whole or in part, because consumers lacked awareness of the alleged actions by Mr. Tucker described in the TAC.

#### TENTH DEFENSE

(Conduct Not Unlawful)

The business practices relating to the allegations in the TAC are not unlawful.

#### ELEVENTH DEFENSE

(Competition Privilege)

Any of Mr. Tucker's alleged actions are protected by the privilege of competition in that Mr. Tucker did not use wrongful means to advance a legitimate interest in competing in the free market.

#### TWELFTH DEFENSE

(Conduct Not Fraudulent Nor Likely To Deceive)

Mr. Tucker's alleged conduct is not fraudulent and was not likely to mislead or deceive consumers and/or the public.

#### THIRTEENTH DEFENSE

(Lack of Materiality)

Plaintiffs' claims based on alleged misrepresentations are barred because the representations alleged by Plaintiffs were not material in that, they were not likely to affect Medi-Span's decisions regarding the listing of the products at issue, and thus were not likely to affect consumers' purchasing decisions. Mr. Tucker's representations and actions alleged in the TAC were not likely to mislead consumers acting reasonably under the circumstances.

#### FOURTEENTH DEFENSE

(Lack of Standing)

Plaintiffs lack either standing and/or capacity to bring some or all of the claims alleged in the TAC.

#### FIFTEENTH DEFENSE

(Negligence and Misconduct of Others)

If there was any negligence or other misconduct proximately causing the damages allegedly sustained by Plaintiffs, such negligence or misconduct was that of parties other than Mr. Tucker, and recovery should be barred or eliminated to that extent.

#### SIXTEENTH DEFENSE

(Adequate Remedy at Law)

Plaintiffs' claims for equitable relief are barred to the extent there is an adequate remedy at law.

#### SEVENTEENTH DEFENSE

(No Right to Injunctive Relief)

To the extent the TAC seeks injunctive relief, Plaintiffs are not entitled to such relief because the hardship that would be imposed on Mr. Tucker and Method, and on the public, by any such relief would be greatly disproportionate to any hardship that Plaintiffs might suffer in its absence. Further, any injunctive relief that would require regulation by this Court on an ongoing basis is inappropriate, and Defendant Method's advertising and marketing activities are already monitored by various federal and state agencies.



EIGHTEENTH DEFENSE

(No Right to Punitive or Exemplary Damages)

Plaintiffs are not entitled to punitive or exemplary damages on any cause of action alleged in the TAC. Any award of punitive or exemplary damages would violate the due process and/or equal protection clause of the United States Constitution.

NINETEENTH DEFENSE

(Lack of Damages)

Plaintiffs have not suffered any damage as a result of any actions allegedly taken by Mr. Tucker, and are thus barred from asserting any claim against Mr. Tucker.

TWENTIETH DEFENSE

(Federal Preemption)

Plaintiffs' claims are expressly and impliedly preempted by federal law, including but not limited to, the Federal Food, Drug, and Cosmetic Act.

TWENTY-FIRST DEFENSE

(Primary/Exclusive Jurisdiction)

Plaintiffs' claims are barred by the doctrines of primary and/or exclusive regulatory agency jurisdiction.

TWENTY-SECOND DEFENSE

(Unclean Hands)

Plaintiffs' claims are barred or abated substantially by the doctrine of unclean hands

TWENTY-THIRD DEFENSE

(Failure to Mitigate)

Without any admission by Mr. Tucker that Plaintiffs suffered injury in any way, to the extent that Plaintiffs did suffer such injury, their claims are barred in whole or in part because they failed to use reasonable means to prevent the alleged damage and failed to use reasonable means to mitigate their damages.

TWENTY-FOURTH DEFENSE

(Reservation)

Mr. Tucker reserves the right to assert additional defenses upon discovery of further information concerning Plaintiffs' claims.

WHEREFORE, Mr. Tucker prays:

1. For a judgment in favor of Mr. Tucker and against Plaintiffs, dismissing the TAC with prejudice;
2. That Mr. Tucker be awarded his costs of suit, including reasonable attorney's fees; and
3. That this Court order such other and further relief in Mr. Tucker's favor as the Court may find just and proper.

Respectfully submitted,

By: /s/ E. Kyle McNew

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*Counsel for Defendant Matthew Scott Tucker*

**Certificate of Service**

I hereby certify that on April 2, 2015, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to all counsel of record.

/s/ E. Kyle McNew

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